

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

BOWERS, RODERICK W. J., et al.

Divisional Application of

Appln. No.: 08/050,032

Group Art Unit: Not Assigned

Confirmation No.:

Examiner: Not Assigned

Filed: February 28, 2002

For: CONTACT LENS MATERIAL

PRELIMINARY AMENDMENT

Commissioner for Patents

Washington, D.C. 20231

Sir:

Prior to examination, please amend the above-identified application as follows:

IN THE CLAIMS:

Please cancel claims 1-16 without prejudice or disclaimer.

Please add the following new claims:

CLAIMS

17. A contact lens material manufactured from a cross-linked polymer formed by polymer using a mixture of;

- a) a zwitterionic monomer;
- b) a non-ionic diluent monomer; and
- c) a cross-linking monomer which forms cross-linking during the polymerisation reaction.

18. A contact lens material according to claim 17 obtained by polymerizing at least 0.2% by weight of said zwitterionic monomer at least 70% by weight of said diluent

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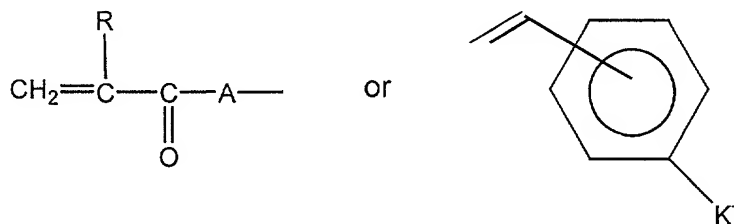
proportions being based on the total weight of monomer.

19. A contact lens material according to claim 17 wherein the zwitterionic monomer has the formula (I):



wherein B is a straight or branched alkylene, oxaalkylene or oligooxaalkylene chain or if X contains a carbon-carbon chain between B and the zwitterionic group or if Y contains a terminal carbon atom, a valence bond,

Y is an ethylenically unsaturated polymerizable group selected from:



wherein

R is hydrogen or a C₁-C₄ alkyl group;

A is -O- or -NR¹- where R¹ is hydrogen or a C₁-C₄ alkyl group or R¹ is -B-X where B and X are as defined above; and

K is a group -(CH₂)_pOC(O)-, -(CH₂)_pC(O)O-, -(CH₂)_pOC(O)O-, -(CH₂)₂NR², -(CH₂)₂NR²C(O)-, -(CH₂)₂C(O)NR²-, -(CH₂)₂NR²C(O)O-, -(CH₂)₂NR²C(O)O-, -(CH₂)₂OC(O)NR²-, -(CH₂)₂NR²C(O)NR²- (in which the groups R² are the same or different), -(CH₂)₂O-, -(CH₂)₂SO₃-, or, optionally in a combination with B, a valence bond, and p is from 1 to 12 and R² is hydrogen or a C₁-C₄ alkyl group; and

X is a zwitterionic group.

20. A contact lens material according to claim 3 wherein X has the general formula IVB, IVC, IVD, IVE or IVF

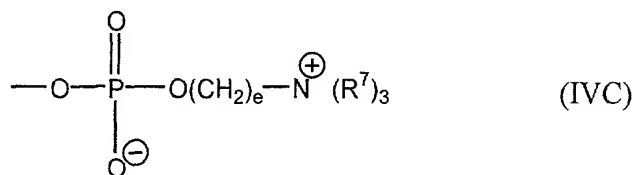
wherein a group IVB has the formula

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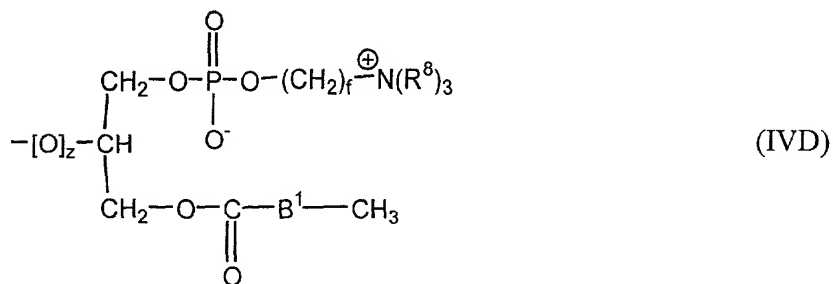
wherein the groups R^6 are the same or different and each is hydrogen or C_{1-4} alkyl and d is from 2 to 4,

the group IVC has the formula



wherein the groups R^7 are the same or different and each is hydrogen or C_{1-4} alkyl, and e is 1, 3 or 4;

groups of formula (IVD) have the general formula

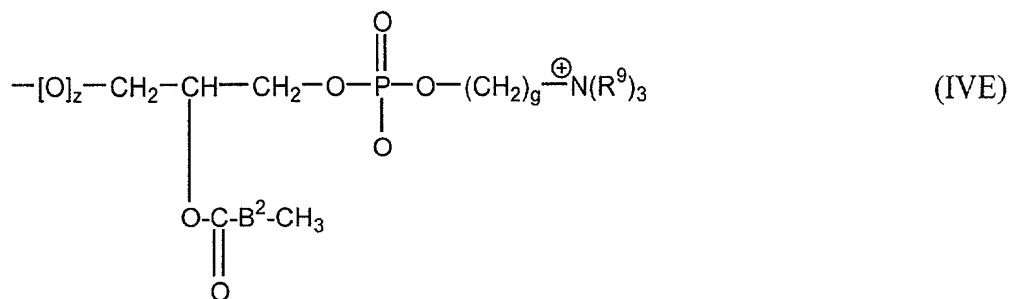


wherein the groups R^8 are the same or different and each is hydrogen or C_{1-4} alkyl, B^1 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, f is

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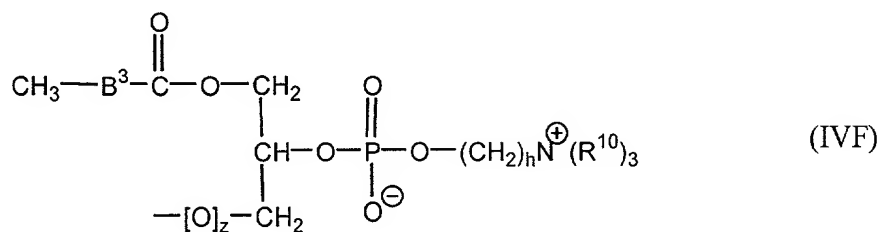
is directly bonded to an oxygen or nitrogen atom and otherwise z is 1;

groups of formula (IVE) have the general formula



wherein the groups R^9 are the same or different and each is hydrogen or C_{1-4} alkyl, B^2 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, g is from 1 to 4 and if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1; and

groups of formula (IVF) have the general formula



wherein the groups R^{10} are the same or different and each is hydrogen or C_{1-4} alkyl, B^3 is a valence bond or a straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, h is from 1 to 4 if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1.

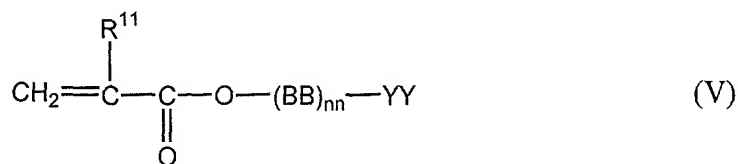
21. A contact lens material, according to claim 20 in which the group X is said group IVC.

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monomer is selected from the group consisting of alkane diol di (alk)acrylates, alkane triol tri(alk)acrylates, alkylene di(alk)acrylamides, alkylene tri(alk)acrylamides, divinylbenzene, and trivinylbenzene.

22 23. A contact lens material according to claim 19 in which the non-ionic monomer is selected from hydroxy C₁₋₄alkyl(alk)acrylates and C₁₋₁₂alkyl(alk)acrylates.

24. A contact lens material according to claim 1 wherein the zwitterionic monomer has the formula (V):



wherein BB is a straight or branched C₁-C₆ alkylene chain optionally interrupted by one or more oxygen atoms;

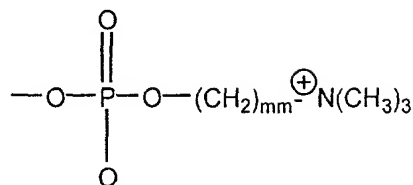
nn is from 1 to 12;

R¹¹ is H or a C₁-C₄ alkyl group; and

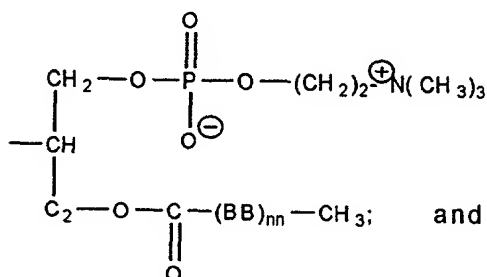
YY is a zwitterionic group.

25. A contact lens material according to claim 24 wherein YY is selected from the group consisting of VIB, VIC, VID and VIE:

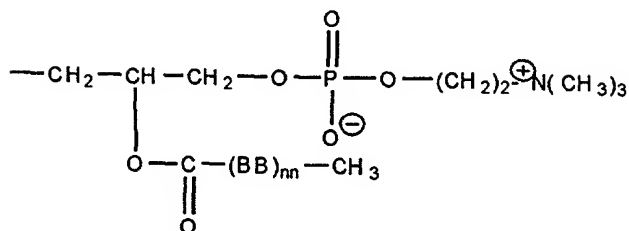




VIC



(VID)



(VIE)

wherein mm is 1 to 4, nn is 1 to 12 and BB is a straight or branched C₁-C₆ alkylene chain optionally interrupted by one or more oxygen atoms.

25 26. A contact lens material according to claim 25 in which YY is a group VIC.

27. A contact lens material according to claim 25 in which the cross-linking monomer which forms cross-links during the polymerization reaction selected from the group consisting of alkane diol di(alk)acrylates, alkane triol tri(alk)acrylates, alkylene di(alk)acrylamides, alkylene tri(alk)acrylamides, divinylbenzene, and trivinylbenzene.

28. A contact lens material according to claim 24 in which the non-ionic monomer is selected from hydroxy C₁₋₄alkyl(alk)acrylates and C₁₋₁₂alkyl(alk)acrylates.

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28 29. A contact lens material according to claim 17 which is a xerogel free of water.

29 30. A contact lens formed of a hydrogel comprising a cross-linked polymer and water in an amount from 30 to 80% by weight.

30 31. A process for making a contact lens comprising providing individual monomers (a), (b) and (c), forming a blend of monomers by dissolving components (b) and (c) into monomer (a) in the absence of non-polymerisable diluent, removing oxygen from the solution, and polymerising the blend in a contact lens mold to form a contact lens which is a xerogel wherein

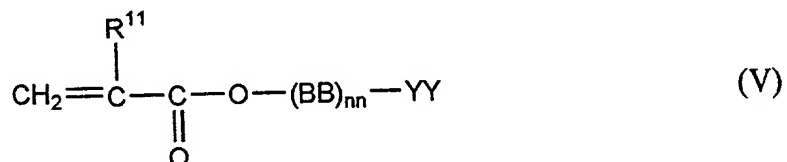
- a) is a zwitterionic monomer,
- b) is a nonionic diluent monomer and
- c) is a cross-linking monomer which forms crosslinks during the polymerisation.

3 32. A process for forming a contact lens material comprising forming a solution of a blend of monomers (a), (b) and (c) in a non-polymerisable solvent, polymerising the monomer blend in a mold and removing the solvent, wherein

- a) is a zwitterionic monomer,
- b) is a nonionic diluent monomer and
- c) is a cross-linking monomer which forms crosslinks during the polymerisation.

3 2 33. A contact lens material manufactured from a cross-linked polymer obtained by polymerizing a mixture consisting essentially of:

zwitterionic monomer of the formula (V):



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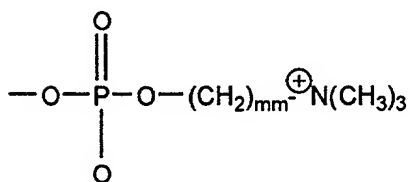
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more oxygen atoms;

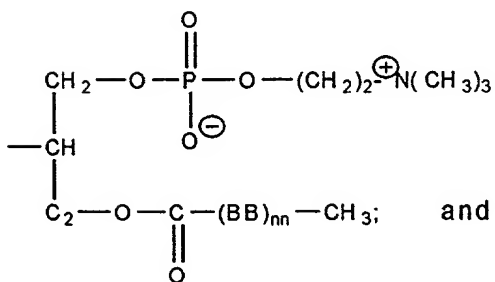
nn is from 1 to 12;

R¹¹ is H or a C₁-C₄ alkyl group; and

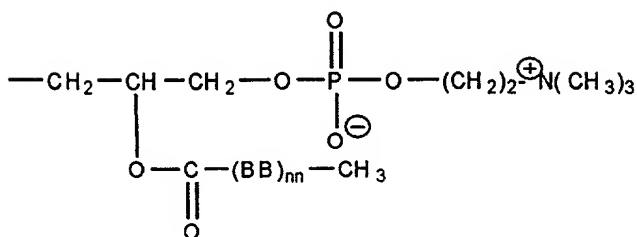
YY is a zwitterionic group which is selected from the group consisting of:



VIC



(VID)



(VIE)

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- ii) a non-ionic diluent monomer; and
- iii) a cross-linking monomer which forms cross-links during the polymerization reaction.

3 3 34. A contact lens material according to claim 33, in which the diluent monomer is selected from the group consisting of alkyl (alk)acrylates, dialkylamino alkyl (alk)acrylates, alkyl (alk)acrylamides, hydroxyalkyl (alk)acrylates, N-vinyl lactams, styrene, substituted styrene, and mixtures thereof.

10084052.0028002 3 35. A contact lens material according to claim 34, in which the diluent monomer is selected from the group consisting of vinyl pyrrolidone, 2-hydroxyethylmethacrylate, methylmethacrylate and mixtures thereof.

5 36. A contact lens material according to claim 35 wherein the diluent monomer is 2-hydroxyethylmethacrylate.

3 6 37. A contact lens material according to claim 35, wherein the diluent monomer is methylmethacrylate.

7 38. A contact lens material according to claim 33, in which the cross-linking monomer is a bifunctional or trifunctional cross-linking agent.

3 8 39. A contact lens material according to claim 38, in which the cross-linking monomer is selected from the group consisting of ethyleneglycoldimethacrylate, trimethylolpropane trimethacrylate and N,N'-methylenebisacrylamide.

3 9 40. A contact lens material according to claim 33, in which YY is a group of formula (VIC).

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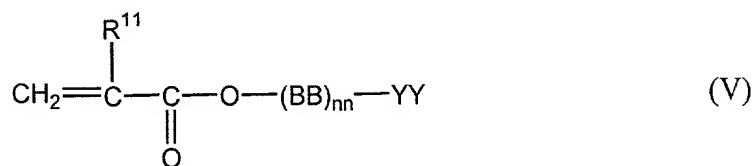
41. A contact lens material according to claim 33, wherein the group R^{11} is hydrogen or methyl.

42. A contact lens material according to claim 33, in which the zwitterionic monomer of the formula V is 2(methacryloyloxy)ethyl-2'-(trimethylammonium)ethyl phosphate inner salt.

43. A contact lens material according to claim 42, in which the diluent monomer is 2-hydroxyethylmethacrylate.

44. A contact lens formed of a hydrogel comprising a cross-linked polymer obtained by polymerizing a mixture consisting essentially of:

i) a zwitterionic monomer of the formula (V):



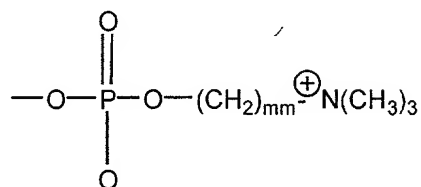
wherein BB is a straight or branched C_1 - C_6 alkylene chain optionally interrupted by one or more oxygen atoms;

nn is from 1 to 12;

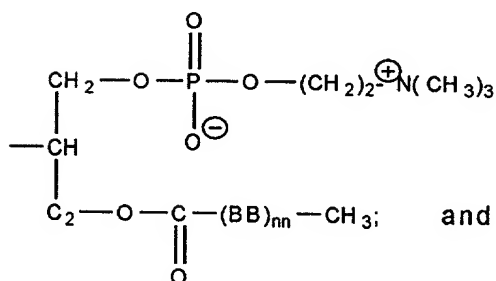
R^{11} is H or a C_1 - C_4 alkyl group; and

YY is a zwitterionic group which is selected from the group consisting of:

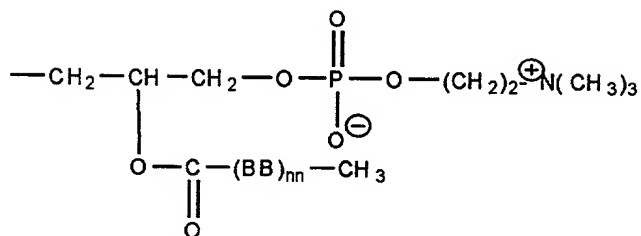
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VIC



(VID)



(VIE)

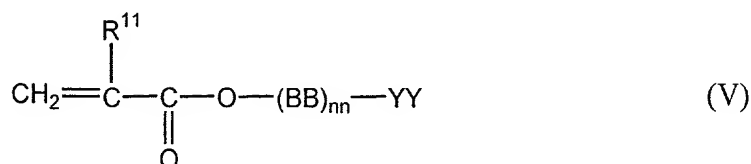
wherein mm is 1 to 4, nn is 1 to 12 and BB is a straight or branched C₁-C₆ alkylene chain optionally interrupted by one or more oxygen atoms;

- ii) a non-ionic diluent monomer; and
- iii) a cross-linking monomer which forms cross-links during the polymerization reaction,

and water in an amount of from 30 to 80% by weight of the hydrogel.

45. A contact lens button formed of a xerogel comprising a cross-linked polymer obtained by polymerizing a mixture consisting essentially of:

- i) a zwitterionic monomer of the formula (V):

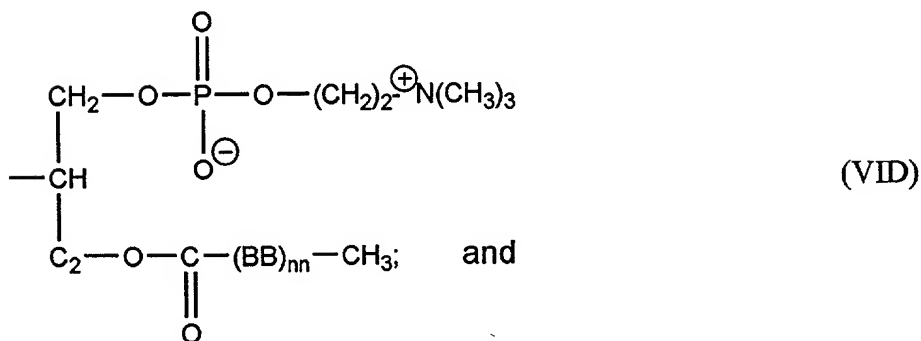
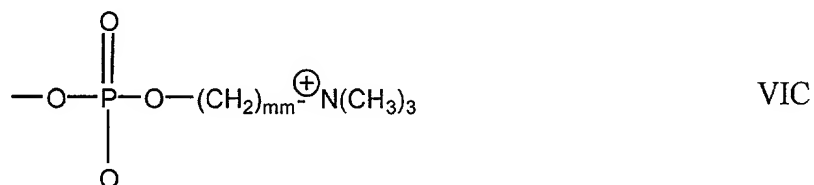


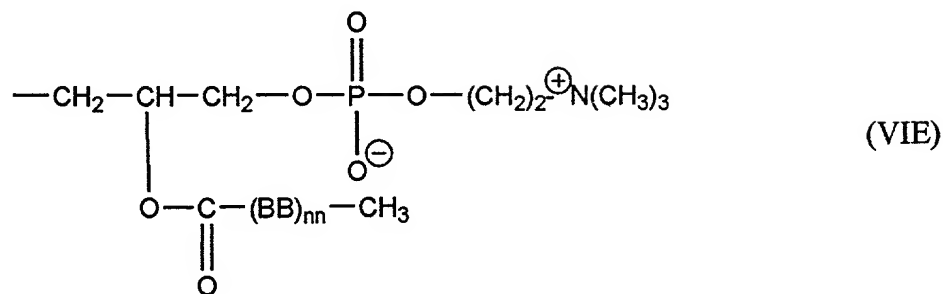
wherein BB is a straight or branched C₁-C₆ alkylene chain optionally interrupted by one or more oxygen atoms;

nn is from 1 to 12;

R¹¹ is H or a C₁-C₄ alkyl group; and

YY is a zwitterionic group which is selected from the group consisting of:





wherein mm is 1 to 4, nn is 1 to 12 and BB is a straight or branched C₁-C₆ alkylene chain optionally interrupted by one or more oxygen atoms;

- ii) a non-ionic diluent monomer; and
- iii) a cross-linking monomer which forms cross-links during the polymerization reaction,

which is free of water.

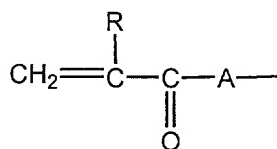
46. A contact lens material manufactured from a cross-linked polymer obtained by polymerizing a mixture consisting essentially of:

- i) a zwitterionic monomer of formula (I):

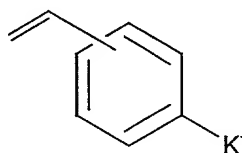


wherein B is a straight or branched alkylene, oxaalkylene or oligo-oxaalkylene chain or if X contains a carbon-carbon chain between B and the zwitterionic group or if K is joined to B via a carbon atom, a valence bond,

Y is an ethylenically unsaturated polymerizable group selected from:
 wherein:



or



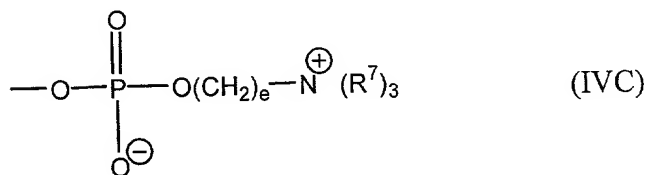
wherein:

R is hydrogen or a C₁-C₄ alkyl group;

A is -O- or -NR¹- where R¹ is hydrogen or a C₁-C₄ alkyl group or R¹ is -B-X where B and X are as defined above; and

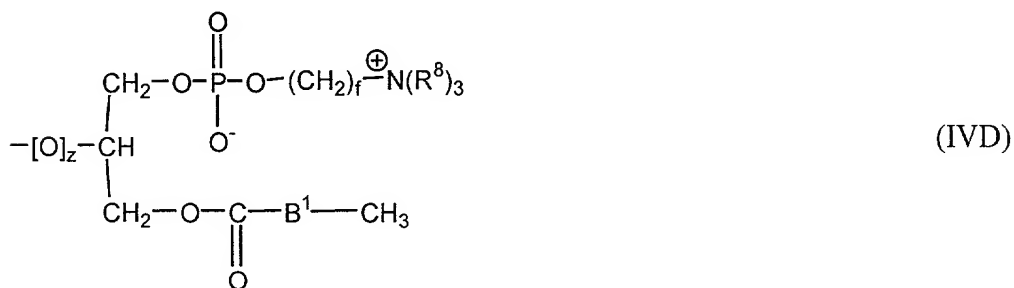
K is a group -(CH₂)_pOC(O)-, -(CH₂)_pC(O)O-, -(CH₂)_pOC(O)O-, -(CH₂)₂NR²-, -(CH₂)₂NR²C(O)-, -(CH₂)₂C(O)NR²-, -(CH₂)₂NR²C(O)O-, -(CH₂)₂OC(O)NR²-, -(CH₂)₂NR₂C(O)NR²- (in which the groups R² are the same or different), -(CH₂)₂O-, -(CH₂)₂SO₃-, or, optionally in a combination with B, a valence bond, and p is from 1 to 12 and R² is hydrogen or a C₁-C₄ alkyl group and

X is selected from the group consisting of groups of formula (IVC):



wherein the groups R⁷ are the same or different and each is hydrogen or C₁₋₄ alkyl, and e is 1, 3 or 4;

groups of formula (IVD):



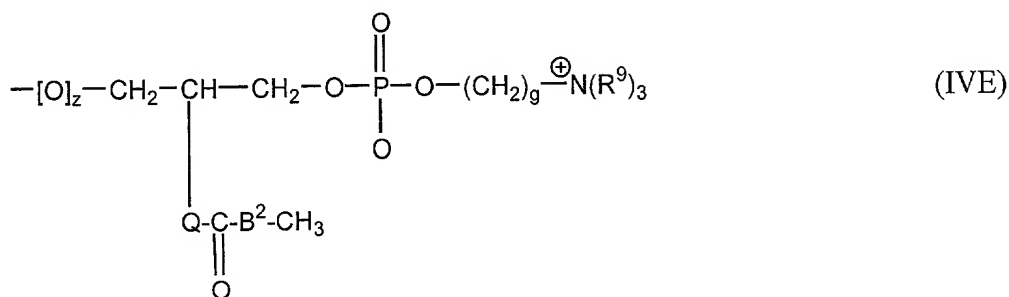
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wherein the groups R^8 are the same or different and each is hydrogen or C_{1-4} alkyl, B^1 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, f is from 1 to 4 and if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1;

groups of formula (IVE):



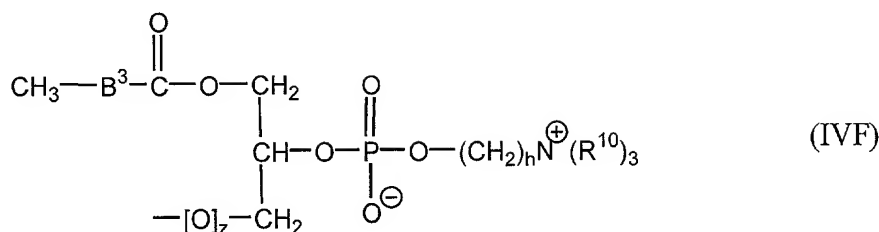
wherein the groups R^9 are the same or different and each is hydrogen or C_{1-4} alkyl, B^2 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, g is from 1 to 4 and if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1; and

groups of formula (IVF):

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wherein the groups R^{10} are the same or different and each is hydrogen or C_{1-4} alkyl, B^3 is a valence bond or a straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, h is from 1 to 4 if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1;

- ii) a non-ionic diluent monomer; and
- iii) a cross-linking monomer which forms cross-links during the polymerization reaction.

47. A contact lens material according to claim 46, in which the diluent monomer is selected from the group consisting of alkyl (alk)acrylates, dialkylamino alkyl (alk)acrylates, alkyl (alk)acrylamides hydroxyalkyl (alk)acrylates, N-vinyl lactams, styrene, substituted styrene, and mixtures thereof.

48. A contact lens material according to claim 47, in which the diluent monomer is selected from the group consisting of vinylpyrrolidone, 2-hydroxyethylmethacrylate, methylmethacrylate and mixtures thereof.

49. A contact lens material according to claim 46, in which B is an alkylene group of formula $-(\text{CR}^3)_a-$, wherein the groups $-(\text{CR}^3)_2-$ are the same or different, and in each group $-(\text{CR}^3)_2-$ the groups R^3 are the same or different and each group R^3 is hydrogen or $\text{C}_1\text{-C}_4$ alkyl, and a is from 1 to 12;

an alkoxyalkyl group having 1 to 6 carbon atoms in each alkyl moiety;

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an oligo-oxaalkylene group of formula $-(\text{CR}^4_2)_b\text{O}(\text{CR}^4_2)_c-$ where the groups $-(\text{CR}^4_2)-$ are the same or different and in each group $-(\text{CR}^4_2)-$ the groups R^4 are the same or different and each group R^4 is hydrogen or $\text{C}_1\text{-C}_4$ alkyl, and b is 2 or 3 and c is from 2 to 11,

or if X contains a carbon-carbon chain between B and the center of positive charge, or if K is joined to B via a carbon atom, a valence bond.

49 50. A contact lens material according to claim 46, in which the group X is a group of formula (IVC).

51. A contact lens material polymer according to claim 50, wherein the groups R^7 are all methyl.

52. A contact lens material according to claim 46, in which cross-linking monomer is a bifunctional or trifunctional cross-linking agent.

53. A contact lens material according to claim 52, in which the cross-linking agent is selected from the group consisting of ethyleneglycoldimethacrylate, trimethylolpropanetrimethacrylate and $\text{N,N}'$ -methylenebisacrylamide.

57 54. A contact lens formed of a hydrogel comprising a cross-linked polymer obtained by polymerizing a mixture consisting essentially of:

i) a zwitterionic monomer of formula (I):

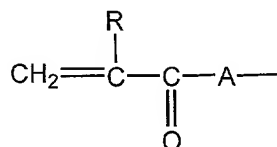


wherein B is a straight or branched alkylene, oxaalkylene or oligo-oxaalkylene chain or if X contains a carbon-carbon chain between B and the zwitterionic group or if K is joined to B via a carbon atom, a valence bond,

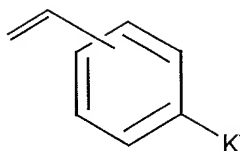
Y is an ethylenically unsaturated polymerizable group selected from:

wherein:

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or



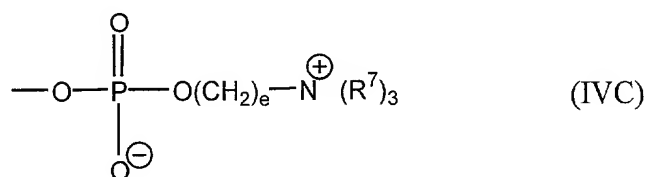
wherein:

R is hydrogen or a C₁-C₄ alkyl group;

A is -O- or -NR¹- where R¹ is hydrogen or a C₁-C₄ alkyl group or R¹ is -B-X where B and X are as defined above; and

K is a group -(CH₂)_pOC(O)-, -(CH₂)_pC(O)O-, -(CH₂)_pOC(O)O-, -(CH₂)₂NR²-, -(CH₂)₂NR²C(O)-, -(CH₂)₂C(O)NR²-, -(CH₂)₂NR²C(O)O-, -(CH₂)₂NR²C(O)O-, -(CH₂)₂OC(O)NR²-, -(CH₂)₂NR₂C(O)NR²- (in which the groups R² are the same or different), -(CH₂)₂O-, -(CH₂)₂SO₃-, or, optionally in a combination with B, a valence bond, and p is from 1 to 12 and R² is hydrogen or a C₁-C₄ alkyl group and

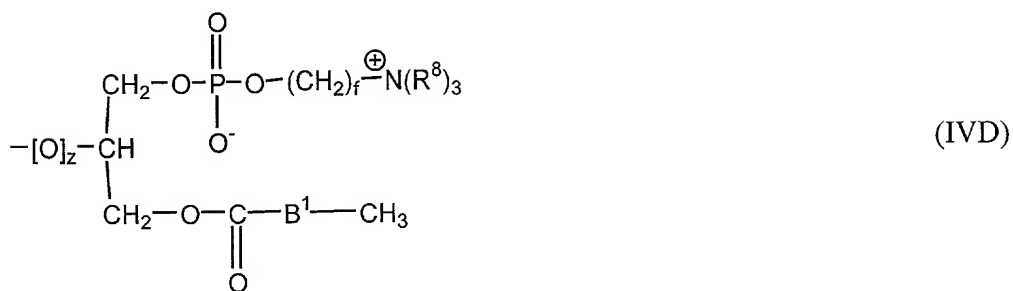
X is selected from the group consisting of groups of formula (IVC):



wherein the groups R⁷ are the same or different and each is hydrogen or C₁₋₄ alkyl, and e is 1, 3 or 4;

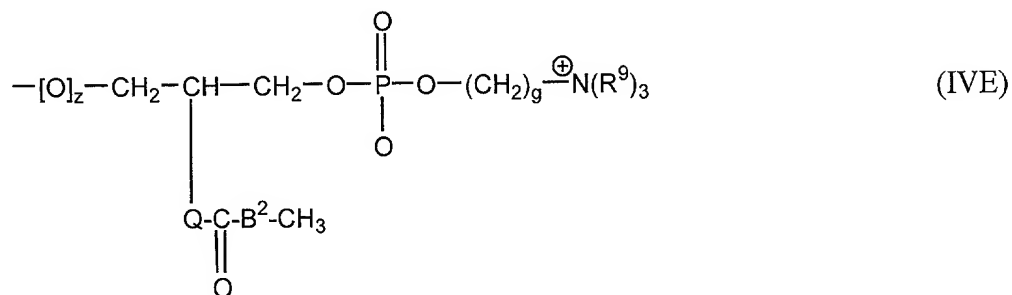
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groups of formula (IVD):



wherein the groups R^8 are the same or different and each is hydrogen or C_{1-14} alkyl, B^1 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, f is from 1 to 4 and if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1;

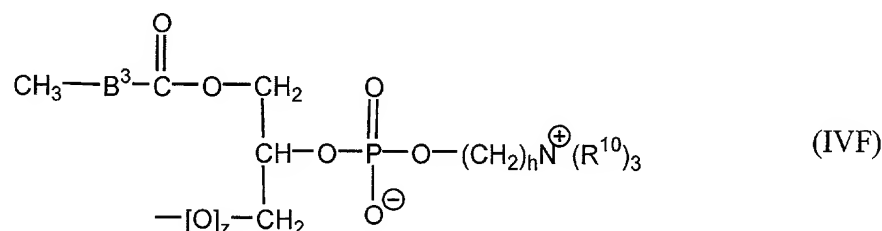
groups of formula (IVE):



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wherein the groups R^9 are the same or different and each is hydrogen or C_{1-4} alkyl, B^2 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, g is from 1 to 4 and if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1; and

groups of formula (IVF):



wherein the groups R^{10} are the same or different and each is hydrogen or C_{1-4} alkyl, B^3 is a valence bond or a straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, h is from 1 to 4 if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1;

- ii) a non-ionic diluent monomer; and
- iii) a cross-linking monomer which forms cross-links during the polymerization reaction,

and water in an amount of from 30 to 80% by weight of the hydrogel.

55. A contact lens button formed of a xerogel comprising a cross-linked polymer cross-linked polymer obtained by polymerizing a mixture consisting essentially of:

- i) a zwitterionic monomer of formula (I):

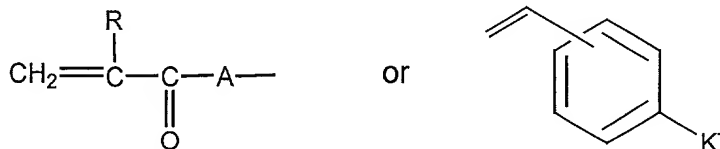
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wherein B is a straight or branched alkylene, oxaalkylene or oligo-oxaalkylene chain or if X contains a carbon-carbon chain between B and the zwitterionic group or if K is joined to B via a carbon atom, a valence bond,

Y is an ethylenically unsaturated polymerizable group selected from:

wherein:



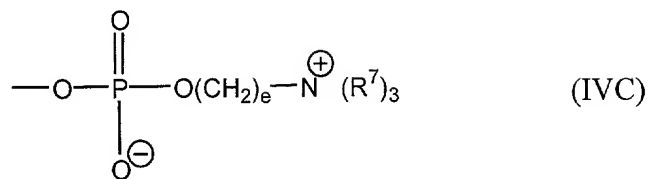
wherein:

R is hydrogen or a C₁-C₄ alkyl group;

A is -O- or -NR¹- where R¹ is hydrogen or a C₁-C₄ alkyl group or R¹ is -B-X where B and X are as defined above; and

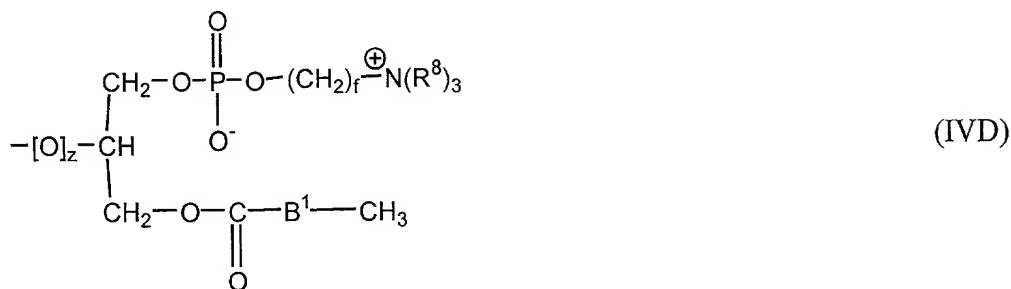
K is a group -(CH₂)_pOC(O)-, -(CH₂)_pC(O)O-, -(CH₂)_pOC(O)O-, -(CH₂)₂NR²-, -(CH₂)₂NR²C(O)-, -(CH₂)₂C(O)NR²-, -(CH₂)₂NR²C(O)O-, -(CH₂)₂NR²C(O)O-, -(CH₂)₂OC(O)NR²-, -(CH₂)₂NR₂C(O)NR²- (in which the groups R² are the same or different), -(CH₂)₂O-, -(CH₂)₂SO₃-, or, optionally in a combination with B, a valence bond, and p is from 1 to 12 and R² is hydrogen or a C₁-C₄ alkyl group and X is selected from the group consisting of groups of formula (IVC):

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wherein the groups R^7 are the same or different and each is hydrogen or C_{1-4} alkyl, and e is 1, 3 or 4;

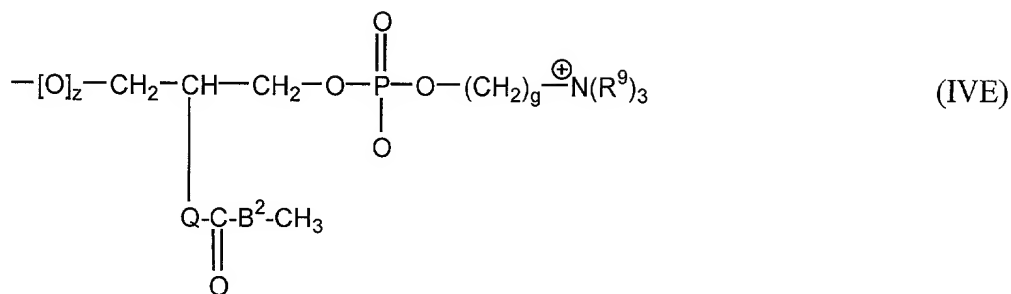
groups of formula (IVD):



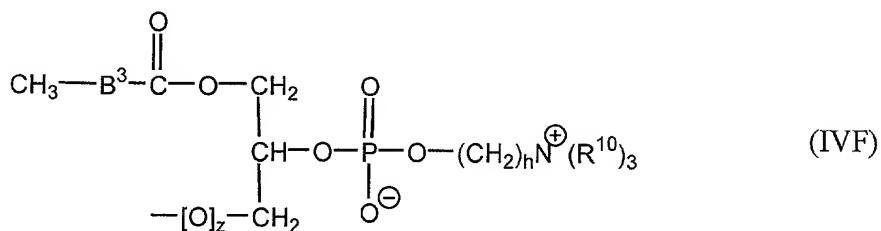
wherein the groups R^8 are the same or different and each is hydrogen or C_{1-4} alkyl, B^1 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, f is from 1 to 4 and if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1;

groups of formula (IVE):

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wherein the groups R^9 are the same or different and each is hydrogen or C_{1-4} alkyl, B^2 is a valence bond or straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, g is from 1 to 4 and if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1; and groups of formula (IVF):



wherein the groups R^{10} are the same or different and each is hydrogen or C_{1-4} alkyl, B^3 is a valence bond or a straight or branched alkylene, oxaalkylene or oligo-oxaalkylene group, h is from 1 to 4 if B is other than a valence bond, z is 1 and if B is a valence bond z is 0 if X is directly bonded to an oxygen or nitrogen atom and otherwise z is 1;

- ii) a non-ionic diluent monomer; and
- iii) a cross-linking monomer which forms cross-links during the polymerization reaction

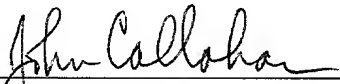
which is free of water.

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REMARKS

Entry and consideration of this Amendment is respectfully requested.

Respectfully submitted,



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Date: February 28, 2002

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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-16 are canceled.

Claims 17-55 are added as new claims

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